Health Canada Santé Canada

Healthy Environments and Consumer Safety

CEPA Assessment for Human Health for Existing Substances The Path to 2006 & Beyond

Bette Meek, Health Canada
www.hc-sc.gc.ca/exsd-dse

Canada

Canadian Environmental Protection Act (CEPA) Existing Substances – the Mandate for Human Health

- Address both exposure and effect to set priorities for risk management
  - Consumer & Environmental Exposure
  - Multimedia
    - Identifying most important media/sources of human exposure
- Publically accountable – transparent process, peer review, documented outcome
- Information gathering, reverse onus provisions, but responsibility of Government for assessment considerable

Potential CEPA Assessment "Feeders" to Identify Priorities for Binational Toxics Strategy

- Priority Substances Lists
  - N= 44 on PSL 1
  - N= 25 on PSL
- Screening Assessments/Pilot
- DSL Categorization
  - Relevance of the "tools"
  - Systematic consideration of potential priorities vs. focus on "data-rich"

Trends in Nature of Substances Considered – PSLs to Categorization/Screening

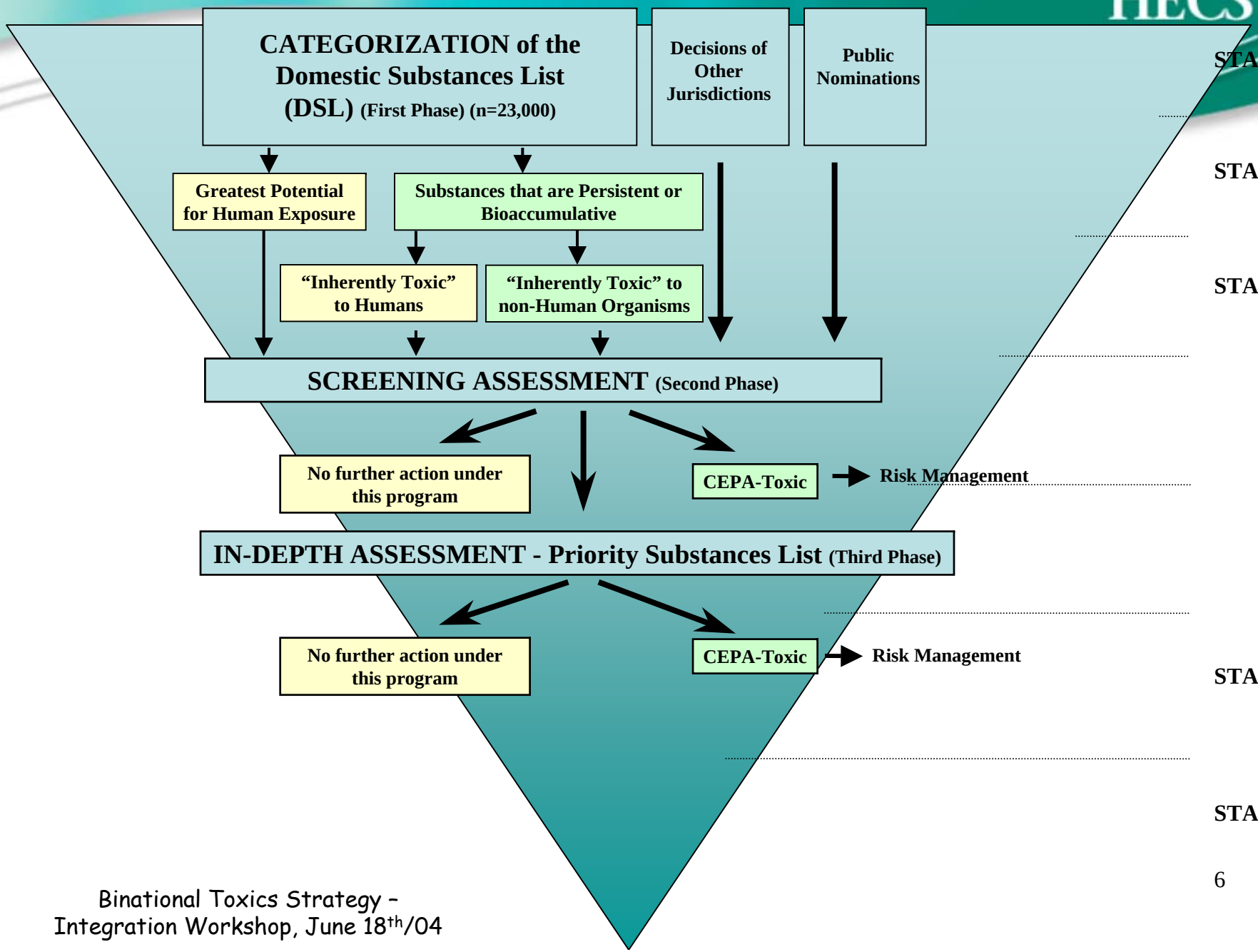
- Limited systematic consideration of candidate substances for PSL 1
- Selection of substances on PSL 2 more systematic based on consideration of much larger numbers of candidates
  - HC systematically considered hundreds of substances (collaborative effort with OMEE)
- However, focus on both PSL 1 & 2 was principally data-rich substances
  - Limited identification of priorities for generation of data on toxicity

Trends in Focus of Assessments - PSLs to Categorization/Screening

- For PSL 1, large numbers of substances where focus was both environmental/health
  - Exception was mixtures
- For PSL 2, trend towards either health or environment being the driver, rather than both
  - E.g., airborne exposures – human health
  - Consumer products/indoor air – human health
  - Mixtures - environmental
- Construct for categorization/screening of DSL reflects this trend
  - Separate health and environmental streams
    - GPE/PorB

CEPA Existing Substances Program

HECS



Screening – the Pilot Phase - Health Components

- Developing models for screening assessments & tools for categorization concomitantly
  - Tools for categorization will simplify screening
- 30 of the 123 substances in the pilot phase for screening are HC nominations
  - Substances selected on basis of "greatest potential for human exposure"
    - High Scoring PSL candidates
    - Emissions (NPRI)
    - Monitoring Data
    - Volume & Use - DSL

What is a Screening Health Assessment? Assessing Substances More Efficiently

- Draws on work completed in other jurisdictions
- Consideration of weight of evidence of hazard and "margins of exposure" which compare upper bounding estimates of exposure to lowest effect levels
  - High hazard, proposed "toxic"
  - Margin wide, "set aside"
  - Margin small, additional assessment
- Decision making on the basis of adequacy of the margins, based on consideration and clear delineation of confidence/uncertainties
  - draws on considerable collective experience within HC (simplified process)

Status of Screening Assessments

Release for Spring 2004:

- PBDEs
- PFOS + precursors

Status of Screening Assessments (cont'd.)

Priorities for 2004

Quinoline (91-22-5)
Biphenyl (92-52-4)
MBMBP (119-47-1)
DNOC (534-52-1)
MBOCA (101-14-4)
1,2-Dibromoethane (106-93-4)
Hexachloroethane (67-72-1)
1,1-Dichloroethylene (75-35-4)

Acetone (67-64-1)
Hydrogen sulphide (7783-06-4)
Ethyl benzene (100-41-4)
TBBPA + derivatives (79-94-7, 25327-89-3, 4162-45-2)
PFOA + salts

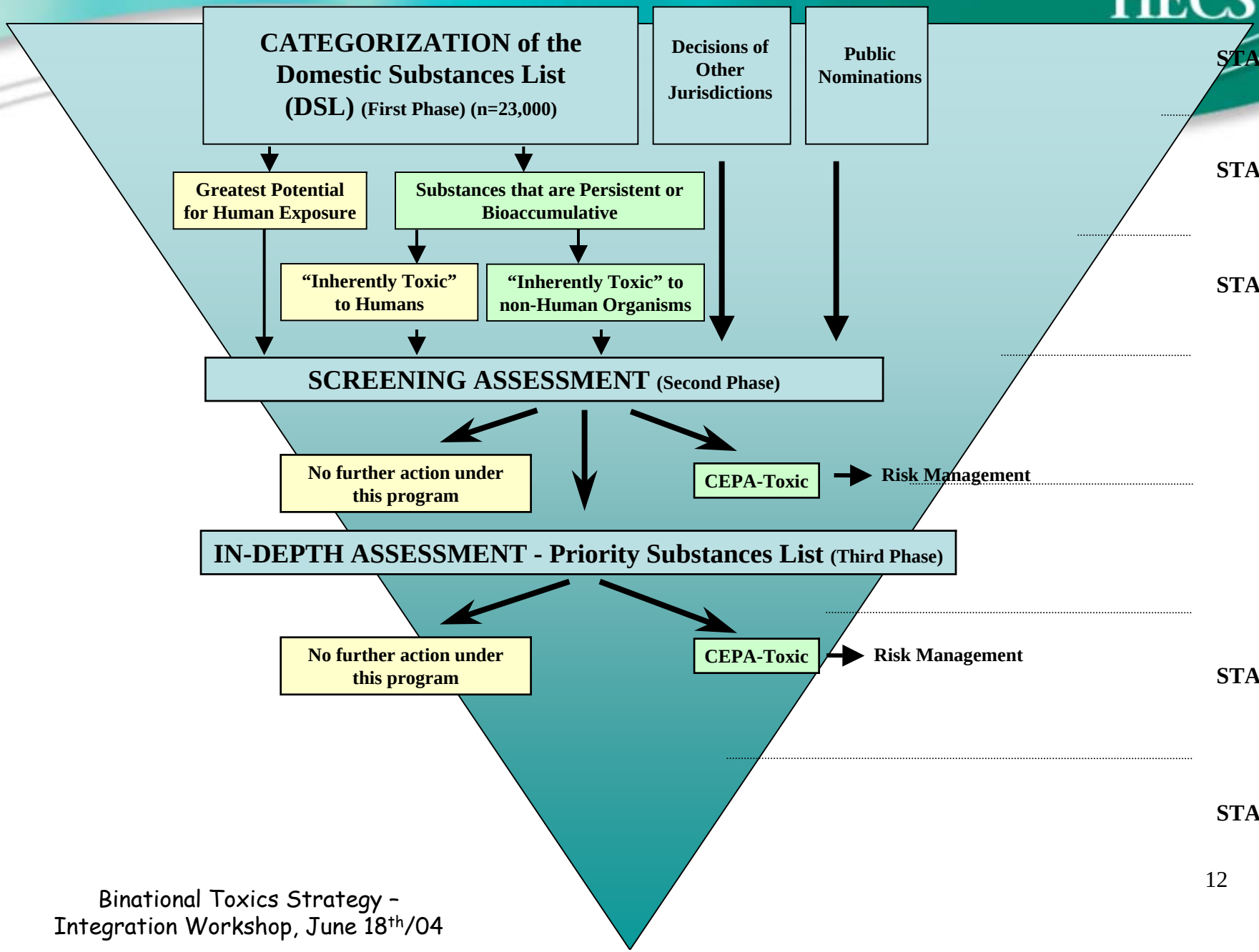
Status of Screening Assessments (cont'd.)

Next:

- 1,2-Dichloropropane (78-87-5)
- 2,4-Dichlorophenol (120-83-2)
- Cedryl acetate (77-54-3)
- Tritolyl phosphate (1330-78-5)
- 2,4-Dinitrophenol (51-28-5)
- Camphene (79-92-5)
- Methyl ethyl ketone (78-93-3)
- Methyl isobutyl ketone (108-10-1)
- 2,4,6-Tri-t-butylphenol (732-26-3)
- 1,2-Bis(2,4,6-tribromophenoxy) ethane (37853-59-1)
- Ethylene (75-85-1
- Decane (124-18-5)
- Hexachlorophene (70-30-4)
- 1,2,4-trimethyl benzene (95-63-6)
- Isopropyl alcohol (67-63-6)
- Chlorine dioxide (10049-04-4)

CEPA Existing Substances Program

HECS



HC Priority Setting (Categorization) of All Existing Substances – Principles/Objectives

- Long Term
  - Tools are critical in meeting the post 2006 mandate for efficiently screening large numbers of Existing Substances
  - Leads to greater consistency in consideration of New versus Existing Substances
- Short Term
  - Simple & Complex tools developed for meaningful & efficient prioritization & assessment (including screening)
  - List of highest priority substances for (screening) assessment
    - Mandated/categorization
    - No more priority setting/assessment than required to "set aside"

Human Health Related Aspects - Categorization

Need to consider:

- "Greatest potential for exposure" (GPE) – all substances
- "Inherently Toxic to humans" (IThuman) – subset of substances
  - Which subset?
    - Those that are P or B (but not ITeco)

Challenge:

- Defining true human health priorities within legislative construct, given that:
- P or B, in themselves, not good surrogates for human exposure
  - Experience in screening
- Exposure/Toxicity define risk
- Consistency with Priority Substances outcomes for high hazard
- Doesn't address how to prioritize beyond 2006

PROPOSED FRAMEWORK FOR HEALTH-RELATED COMPONENTS OF DSL CATEGORIZATION

HECS

DOMESTIC SUBSTANCES LIST

HEALTH CANADA

ENVIRONMENT CANADA

DSL Substances Ranked According to Potential For Exposure

Highest

Lowest

DSL Substances Identified as Hazardous to Human Health

Substances that are Persistent and/or Bioaccumulative According to the Regulations

Substances that are Persistent and/or Bioaccumulative and Not "Inherently Toxic" to Non-human Organisms

Substances that are Persistent and/or Bioaccumulative and "Inherently Toxic" to Non-human Organisms

Health Canada Substances for Screening Assessment Prioritized on the Basis of Potential Risk to Human Health (Exposure & Toxicity)

EC Substances Identified for Screening Assessment

High — Low

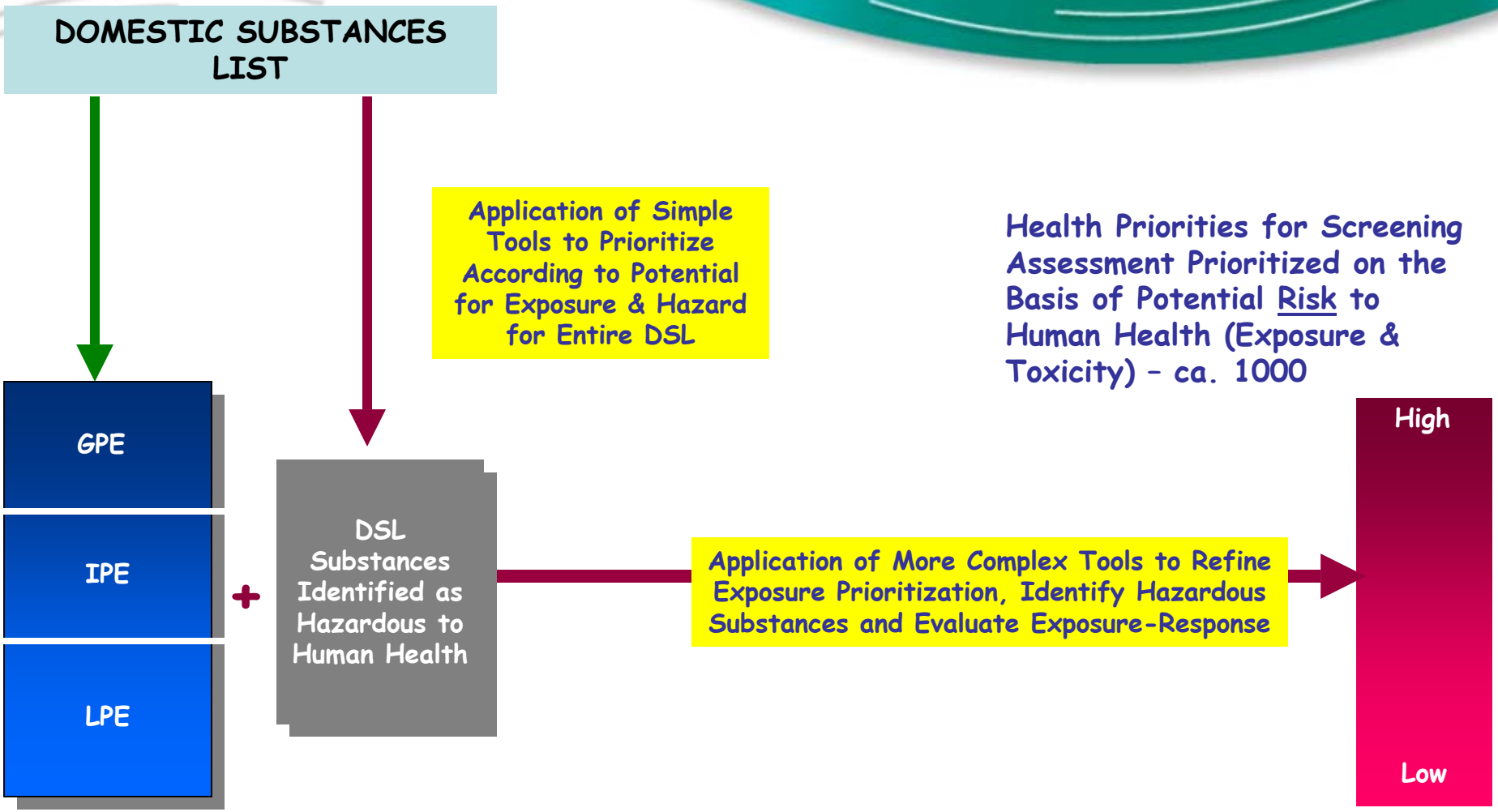
Binational Toxics Strategy – Integration Workshop, June 18th/04

Efficiently Identifying Highest Priorities from a Human Health Perspective - Approach

- Initial application of simple, discriminating tool on exposure to address all 23,000 substances to prioritize - "greatest potential for exposure" (GPE), "intermediate potential for exposure" (IPE) & "lowest potential for exposure" (LPE)
- Application of simple, discriminating tool to address hazard for all 23,000 substances
- Priority-based application of more complex tools to additionally refine list & order of priorities
  - Exposure, dose-response
- Addressing all groups of substances concurrently
  - UVCBs most difficult, requiring multiple steps

PROPOSED APPROACH FOR HEALTH-RELATED COMPONENTS OF DSL CATEGORIZATION

HECS



Simple & Complex Exposure & Hazard Tools – What's the Difference?

- Simple hazard tools bias to selection of data-rich compounds
  - i.e., all compounds are not treated the same way
- Complex hazard tools address all compounds in the same manner, thereby identifying those which are priorities for both data generation and assessment
- Simple exposure tools are based on more limited information available for all substances

Categorization – Human Health – Products in 2006 & Advantages

- Meets legal obligation to identify substances with "greatest potential for exposure" (GPE) and a subset for "Inherently Toxic to humans" (IThuman), by developing
  - List for screening **prioritized** on the basis of potential risk (categorized "in")
- Tools developed to permit efficient screening
- Unbiassed in relation to data availability for highest priorities
- Concepts well supported
- Declared priorities to focus input of industrial stakeholders

The Plan to 2006 – Health Components of Categorization/Screening

- GPE proposal released last Autumn
  - Information session, public comment
- Communication re proposed content of second proposal on health priorities to ensure understanding including meetings with stakeholders & additional information session
  - May – Autumn/04
- Draft Integrated Proposal – GPE and IT Human & draft categorization list for health priorities
  - Autumn/04
- Refined/Final Integrated Proposal for Health Priorities
  - Sept./05

Screening: HC nominated substances prioritized for completion in the pilot phase

Categorization – What do we need most from Industrial Stakeholders?

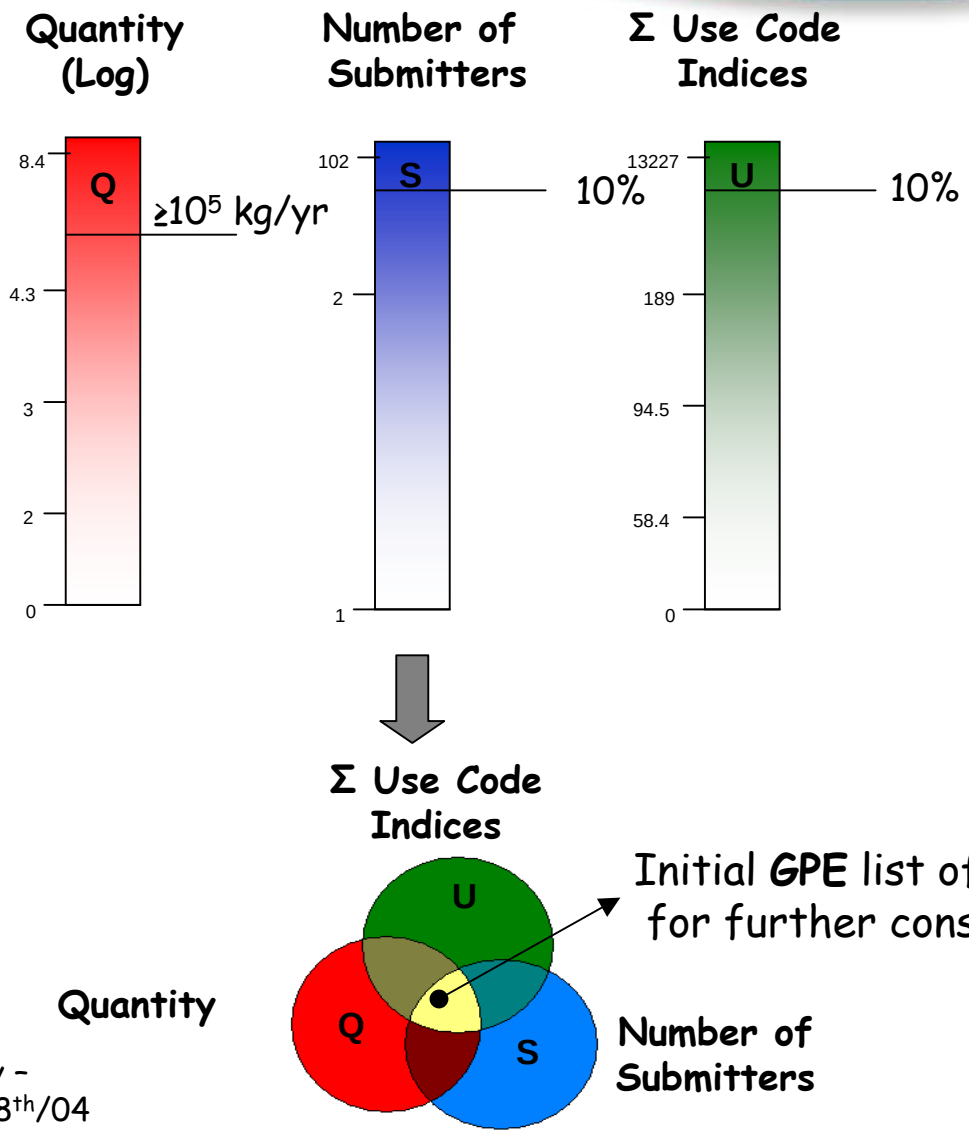
Information Shared with the ICG:

- Data on Composition and Use
  - **Chemical Composition & Toxicity – specific GPE & IPE UVCBs**
  - **Information on specific GPE polymers similar to that in New Substances**
  - **Input on Use for Development of ComET**
- Forward looking products in the peer reviewed literature addressing critical areas that can be taken into consideration
  - **Exposure scenarios/modelling**
  - **QSAR development**

DSL CATEGORIZATION – TOOLS - HEALTH

Exposure	Hazard [High (H) or Low (L)]
•SimET (Relative ranking of all DSL substances based on submitters (S),quantity (Q) and expert ranked use (ERU) •ComET (Quantitative upper bound exposure estimate based upon use scenario, phys/chem properties & bioavailability) Others… •ChID (Chemical ID) for UVCBs •environmental degradation/metabolism	•SimOthLIST (eg., European CMR List; List 4A-Pesticide Formulants) – H, L •Hierarchical Approach for Multiple Endpoints – L,H (latter, when combined with other tools) •QSAR weight of evidence for cancer/genotoxicity – H,L •Functional Groups – Polymers – H, L

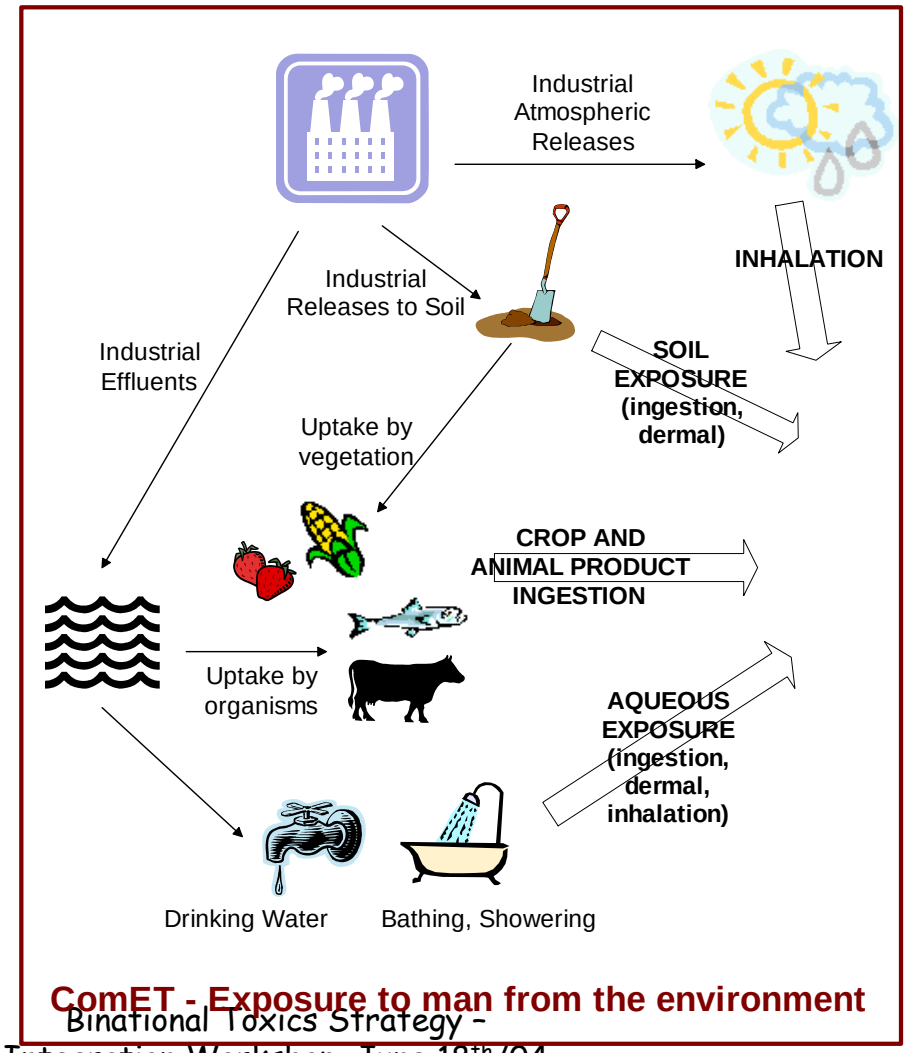
Simple Exposure Tool (SimET): Relative Ranking for all DSL substances



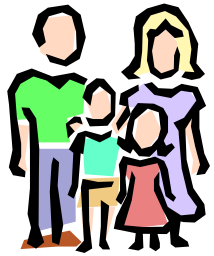
Criteria for Greatest, Intermediate and Lowest Potential for Exposure (GPE, IPE & LPE)

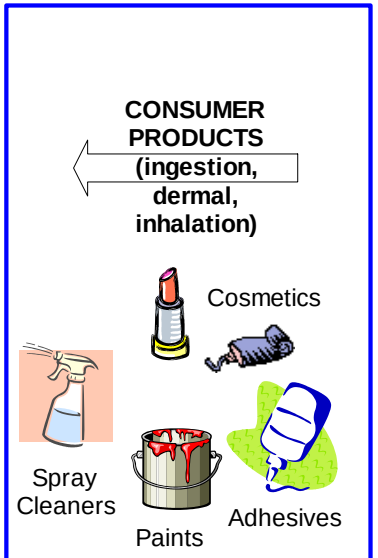
	Quantity (kg/year)	Number of Submitters	Sum of the Expert Ranked Use Code Indices
GPE	> 100 000	Top 10%	Top 10%
IPE	> 10 000	n.a.	Top 30%
LPE	All	All	All

Complex Exposure Tool (ComET)



ComET - Exposure to man from the environment





ComET - Near-field exposures

Objectives of ComET – Existing Substances

- Encompassing model for consumer/environmental exposure
  - considerably more inclusive than previous initiatives
- Upper bound quantitative estimates of combined consumer & multimedia environmental exposure for various durations and age groups, taking into account accessible information on:
  - Use categories, representative ("sentinel") product scenarios
    - Driven by DSL "Use Codes"
  - Physical/chemical properties
  - Bioavailability
  - Emissions

Complex Tool - Weight of Evidence – QSAR - Cancer/Genotoxicity

- Human health endpoints for which we have greatest confidence in QSAR, owing principally to availability of data from simple screening assays
- Potential to combine multiple endpoints
- Weight of evidence to take into account considerations of:
  - Endpoints,
  - Characteristics of suite of Models/Submodels

Outputs of Existing Substances Program Relevant to Identification of Priorities for Binational Toxics Strategy

- Hundreds of assessed compounds
  - PSLs, screening
- For thousands of compounds, risk-based priority setting for human health
  - DSL categorization
- Tools developed to prioritize substances for monitoring, testing, assessment & control
  - Exposure, QSAR

DSL Emerging Patterns Relevant to Identification of Priorities for Binational Toxics Strategy

- Experience with the two separate streams of categorization and in screening for health versus environmental priorities
- Multimedia exposure assessments including products
- Human exposure best characterized by sources/emissions/use patterns
  - Importance of "near-field" exposures
    - Indoor air, consumer products
- While bioaccumulation potential can contribute to human exposure in the environment, persistence not a good surrogate for human exposure or toxicity

Voluntary Children's Chemical Evaluation Program (VCCEP) – Pilot Substances (n=23)

On PSLs (n=9):

- Benzene, TCE, TeCE, o, m-xylene, CB, p,m-DCB, toluene

On Pilot Phase for Screening (n=9):

- Acetone, MEK, ethylbenzene, EDB, EDC, decane, PBDEs (penta, octa, deca)

Other (n=5):

- Vinylidine Chloride, a-pinene, n-dodecane, p-dioxane, undecane

DSL Emerging Patterns Relevant to Identification of Priorities for Binational Toxics Strategy (Cont'd)

- For human health **&** environmental protection, consider:
  - compounds with varied & large number of sources/considerable use & emissions (GPE)
  - which are also persistent and bioaccumulative (P&B)
  - and toxic to health and the environment
    - Nature of these compounds sometimes varies for ecological vs. human health

What do we Know About These Priorities Currently?

- Likely priorities for early consideration beyond the pilot phase:
- Subset of limited number of compounds in the DSL categorization exercise having "Greatest Potential for Human Exposure" (GPE) that are P & B & IThuman & IT eco
  - based on systematic consideration of much larger numbers of substances than previously
- While not yet finalized, based on early perusal, several of the compounds included in this subset have already been assessed on PSLs

More Information?

- Existing Substances Division Website – http://www.hc-sc.gc.ca/exsd-dse
- Health Canada Greatest Potential for Exposure Proposal – http://www.hc-sc.gc.ca/hecs-sesc/exsd/categorization_dsl_human_exposure.htm
- Health Canada Existing Substances Mailing List – http://www.hc-sc.gc.ca/hecs-sesc/exsd/listserv.htm
- Screening Health Assessment – http://www.hc-sc.gc.ca/hecs-sesc/exsd/screening_assessment_of_existing_sub.htm
- Additional Inquiries – ExSD@hc-sc.gc.ca